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| 10/089,879 | 08/12/2002 | Pieter Cornelis Langeveld | 246152016800 | 1306 |
| 7590 12/20/2005 | | | EXAMINER | |
| Kate H Murashige Morrison & Foerster Suite 500 3811 Valley Centre Drive San Diego, CA 92130-2332 | | | ZEMAN, ROBERT A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,879

Applicant(s)

LANGEVELD ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005 and 07 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment and response filed on 4-18-2005 are acknowledged. Claims 1, 6 and 12 have been amended. Claims 8 and 11 have been canceled. Claim 13 has been added. Claims 1-6 and 12-13 are pending and currently under examination.

The response to the information request made under Rule 105 is acknowledged and is addressed below.

The terminal disclaimer filed on 4-18-2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Number 10/089,874 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections Withdrawn

The provisional rejection of claims 1-6 and 12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 14-16 of copending Application No. 10/089,874 is withdrawn in light of the Terminal Disclaimer filed on 4-18-2005.

The rejection of claims 1 and 12 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "any natural inhibiting compound" is withdrawn in light of the amendment thereto.

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "indicators" is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 112

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “test suitable for determining the presence or absence of an antimicrobial residue...” is maintained. The amendment to claim 1 is insufficient to overcome said rejection as it is unclear how the results of a composition can be based on microbial growth and how this correlates to the aforementioned term.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 6 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Charm et al. (U.S. Patent 5,354,663) for essentially the reasons set forth in the previous Office action in the rejection of claims 1, 6 and 12.

Applicant argues:

1. Charm does not disclose the order of steps as claimed. Specifically, present claim 1 step ii) requires heating the contacted sample and test composition to inactivate any inhibiting compound. Hence step i) must occur before step ii). Charm does not disclose such a step.

Applicant's arguments have been fully considered and deemed unpersuasive.

Charm et al. disclose a method for the determination of the presence of antimicrobial drugs in samples, the method comprising placing a sample into a container and heating the sample to a temperature of about 100 °C for one to five minutes, a temperature and time sufficient to destroy at least some of the natural inhibitors in the sample (see col. 3, lines 32-39). The method further comprises adding a test (test organism, i.e., a tablet of *Bacillus stearothermophilus*, the same organism as Appellants' test organism) to the sample, heating the mixture of the sample and the test to about 100 °C for 0.1 to two minutes (see column 3, lines 50-53), and incubating the mixture containing the sample and the test to determine whether or not microbial growth occurs (see column 3, lines 32-68).

Applicant argues that the steps of claim 1 must be performed in the recited order. Nevertheless, as noted above, Charm et al. disclose that the food or animal-derived sample may be heated with or without the test organism to inactivate any natural disturbing compound in the sample. During the second heating step, no interaction or reaction occurs between the test organism and the sample. It is plain that heating serves both to heat-shock the test organism (present as spores) and to inactivate any natural disturbing compound in the sample. Further, the open comprising language of the instant claims does not exclude additional steps, such as a second inactivating step. Whether the sample is heated once or twice before incubating it with the test organism, the result is the same. Applicant has not shown that the absence of a second inactivating step produces a different result. Both Charm et al. and Applicant perform the same steps in their methods and achieve the same result.

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Claims 1-6, 12 and newly added claim 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Inglis et al. (Journal Assoc. Off. Anal. Chem. Vol. 61, No.5, 1978, pages 1098-1102 – IDS).

Applicant argues:

1. Inglis et al. does not disclose that the sample and the test are heated to destroy any inhibitors.

Applicant's arguments have been fully considered and deemed unpersuasive.

The instant claims require that the sample and a "test composition" be heated to destroy inhibitors. Inglis et al. disclose that the samples are combined with a surfactant buffer prior to heating. Since said buffer constitutes a "test composition", a holding of anticipation is proper and is therefor maintained.

As outlined previously, Inglis et al. disclose an assay procedure for detecting antimicrobial residues (streptomycin) in egg samples wherein said samples and test organism (spores) are heated to 85 degrees for 15 minutes and subsequently added to agar plates for determine whether spore growth was inhibited. Inhibition of said growth is indicative of the presence of an antimicrobial residue (see Method section on pages 1098-1099). Moreover, Inglis et al. specifically disclose that the heating step was to inactivate lysozyme activity (natural inhibiting compound)[see abstract].

Claims 1-6, 12 and newly added claim 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Katz et al. (Journal Assoc. Off. Anal. Chem. Vol. 61, No.5, 1978, pages 1103-1106 – IDS).

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Applicant argues:

1. Katz et al. do not disclose that the sample and the test are heated to destroy any inhibitors.

Applicant's arguments have been fully considered and deemed unpersuasive.

The instant claims require that the sample and a "test composition" be heated to destroy inhibitors. Katz et al. disclose that the samples are combined with a surfactant buffer prior to heating. Since said buffer constitutes a "test composition", a holding of anticipation is proper and is therefor maintained.

As outlined previously, Katz et al. disclose an assay procedure for detecting antimicrobial residues (neomycin) in egg samples wherein said samples and test organism (spores) are heated to 85 degrees for 15 minutes and subsequently added to agar plates for determine whether spore growth was inhibited. Inhibition of said growth is indicative of the presence of an antimicrobial residue (see Method section on pages 1103-1104). Moreover, Katz et al. specifically disclose that the heating step was to inactivate lysozyme activity (natural inhibiting compound)[see abstract].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 12 and newly added claim 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al. (U.S. Patent 5,354,663).

Charm discloses a test method for the determination of antimicrobial drugs in food samples, in which the test method includes placing a sample into a container and heating the sample to a temperature sufficiently high to destroy the natural inhibitors in the sample. The method further comprises adding a test to the sample and incubating the mixture containing the sample and the test to determine whether or not microbial growth occurs (see column 3, line 27, to column 4, line 10, in particular, column 3, lines 32-35). Charm et al. differs from the instant invention in that they do not explicitly disclose the temperature range and duration of heating with regard to samples comprising eggs. However, since Charm et al. disclose that samples need to be heated to a temperature sufficiently high to destroy the natural inhibitors in the sample, the claimed temperature ranges and durations constitute an optimization of the disclosed method. The skilled artisan would necessarily adjust the temperature and heating duration for a given sample type.

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Applicant argues:

1. Charm does not disclose the order of steps as claimed. Specifically, present claim 1 step ii) requires heating the contacted sample and test composition to inactivate any inhibiting compound. Hence step i) must occur before step ii). Charm dose not disclose such a step.

Applicant's arguments have been fully considered and deemed unpersuasive.

Charm et al. disclose a method for the determination of the presence of antimicrobial drugs in samples, the method comprising placing a sample into a container and heating the sample to a temperature of about 100 °C for one to five minutes, a temperature and time sufficient to destroy at least some of the natural inhibitors in the sample (see col. 3, lines 32-39). The method further comprises adding a test (test organism, i.e., a tablet of *Bacillus stearothermophilus*, the same organism as Appellants' test organism) to the sample, heating the mixture of the sample and the test to about 100 °C for 0.1 to two minutes (see column 3, lines 50-53), and incubating the mixture containing the sample and the test to determine whether or not microbial growth occurs (see column 3, lines 32-68).

Applicant argues that the steps of claim 1 must be performed in the recited order. Nevertheless, as noted above, Charm et al. disclose that the food or animal-derived sample may be heated with or without the test organism to inactivate any natural disturbing compound in the sample. During the second heating step, no interaction or reaction occurs between the test organism and the sample. It is plain that heating serves both to heat-shock the test organism (present as spores) and to inactivate any natural disturbing compound in the sample. Further, the open comprising language of the instant claims does not exclude additional steps, such as a second inactivating step. Whether the sample is heated once or twice before incubating it with the test organism, the

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result is the same. Applicant has not shown that the absence of a second inactivating step produces a different result. Both Charm et al. and Applicant perform the same steps in their methods and achieve the same result.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claim 12 to recite, “natural compound inhibiting microbial growth”. This phrase does not appear in the specification, or original claims as filed. The portion of the specification cite by Applicant for the basis for this limitation in the application does not support said limitation. Said portion of the specification deals with antimicrobial substances. No mention of “natural compounds” is made and none is apparent in the specification. Therefore this limitation is new matter.

Claims 1-6 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The method steps set forth in the rejected claims seem to render said method inoperative. Step (ii) of claim 1 requires that the test sample and the test composition to be heated until any compound that inhibits microbial growth in the sample is inactivated. This would encompass not only the antimicrobial substances that lead to false positives but also the antimicrobial residues that are to be detected. Consequently, one would not be able to get a positive result (i.e. detect an antimicrobial residue) utilizing the recited method steps.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 recites the limitation "test" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "natural compound inhibiting microbial growth" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 12-13 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention. The method that constitutes the instant invention is disclosed in the instruction sheet for the Premi[®]Test sample procedure for eggs (Exhibit B of Applicant's response filed on 10-7-2005). The procedure set forth in said instruction sheet anticipates all the limitations of the instant claims. Moreover, it is apparent the Premi[®]Test was publicly disclosed prior to the priority date of the instant application as evidenced by Geijp et al. (Abstract book "Third International Symposium of Hormone and Veterinary Drug Residue Analysis, Brugge", 1998).

An issue of public use or on sale activity has been raised in this application. In order for the examiner to properly consider patentability of the claimed invention under 35 U.S.C. 102(b), additional information regarding this issue is required as follows: the date the Premi[®]Test became publicly available. The date the insert (exemplified by Exhibit B) was originally released.

Applicant is reminded that failure to fully reply to this requirement for information will result in a holding of abandonment.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ROBERT A. ZEMAN
PATENT EXAMINER

December 13, 2005